

<b>QM-06</b>	<b>Resource Management</b>		
<b>Issued by: Quality Assurance</b>	<b>Effective Date: 6/6/2011</b>	<b>Rev. A</b>	<b>Pg. 1 of 5</b>
Approved: 6/6/2011 5:48 PM - Alan Halko, Quality Manager			

## 6.1 PROVISION OF RESOURCES

*As the standard does not prescribe any specific methods for determining resource requirements and provision of resources, this section tries to be as general and noncommittal as possible. If you are a small company and do not use any specific methods for formal identification and allocation of resources, this section should be sufficient as is. However, if you have formal systems for managers to request additional space, equipment, personnel, etc., and/or a formal process for establishing budgets, this is the place to document such systems.*

*In this quality system, matters regarding resources are periodically reviewed and determined in the framework of management reviews. This is at no cost to the system, as Clause 5.6.3.c) already requires that management review output must include decisions regarding resource needs.*

- 6.1.1 Resources required for implementing, maintaining and improving the quality management system, and for addressing customer satisfaction, include personnel, infrastructure, work environment, process equipment, materials, information, and financial resources.

*If you only need to comply with ISO 13485 (no ISO 9001), you can change "...for implementing, maintaining and improving the quality system, and for addressing customer satisfaction ." to "...for implementing the quality management system and maintaining its effectiveness and for meeting regulatory and customer requirements "*

- 6.1.2 Determination of resource needs for specific activities is integrated with the process of defining and initiating the activity. It may take the form of personnel assignments, allocation of space or equipment, training, procurement decisions, budgets, etc.

- 6.1.3 Depending on the type and nature of the operation or activity, resource requirements are defined in:

- Quality manual, operational procedures and work instructions (***QOP-42-01 Document Control***);
- Product and process drawings and specifications (***QOP-42-02 Device Master Record***);
- Production plans (***QOP-75-01 Production Work Order and History Record***);

*This reference is specifically to the work order or traveler, where human/equipment/process resources are called out for every operation.*

- Job descriptions, competence matrixes, and training programs (***QOP-62-01 Competence, Awareness and Training***);
- Minutes of management reviews, quality objective records, and corrective and preventive action requests (***QOP-56-01 Management Review, QOP 85-04 Corrective and Preventive Action***).

- 6.1.4 Top management has the responsibility and authority for provision of resources.

- 6.1.5 Management reviews of the quality system are the principal forum for determining resource requirements and providing resources for maintaining and improving the quality system, and for enhancing customer satisfaction. Operational Procedure ***QOP-56-01 Management***

*Review* defines this process.

*If you only need to comply with ISO 13485 (no ISO 9001), you can take out any references to "improvement" and to "customer satisfaction".*

## 6.2 HUMAN RESOURCES

*This section of the manual consists basically of some general verbiage paraphrasing Clause 6.2 of the standard, assignment of general responsibilities, and a reference to operational procedure QOP-62-01, Training and Awareness. Make sure that you edit the assignment of responsibilities (6.2.1.2 and 6.2.1.3) to fit your company.*

### 6.2.1 General

6.2.1.1 Personnel performing work affecting product quality are competent. Competence is determined on the basis of appropriate education, training, skills and experience.

6.2.1.2 **<Human Resources>** department is responsible for training and awareness programs for company-wide participation, such as: general orientation, rules and regulations, quality system, safety, and other company-wide systems and issues.

6.2.1.3 Departmental managers are responsible for identifying competency requirements and for providing training in their departments. Departmental training is primarily focused on increasing the level of skills in operating equipment and processes, conducting inspections and testing, using analytical and statistical techniques, and other such skills as appropriate for particular positions and jobs.

### 6.2.2 Competence, awareness and training

6.2.2.1 Processes for ensuring adequate competency and awareness of personnel are defined in Operational Procedure **QOP-62-01 Competence, Awareness and Training**. The procedure addresses issues related to:

- Determining competency requirements,
- Identifying training needs,

*If you don't need to comply with CFR 820, you can delete this bullet.*

- Providing training,
- Evaluating the effectiveness of training,
- Ensuring quality awareness, and
- Maintaining training records.

## 6.3 INFRASTRUCTURE

*ISO 13485 Clause 6.3 applies only to those facilities, equipment and supporting services that have direct bearing on the organization's ability to ensure product conformity. In other words, the clause applies only when inadequacy or deterioration of a facility, or breakdown of a service could directly result in nonconforming product.*

*Obviously, production process equipment and product delivery services would almost always fall into this category. Examples of other types of facilities and services that could be relevant are buildings, warehouses, workstations, utilities, ventilation and air filtering*

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*systems, communication, IT services, etc.*

*This documentation takes the usual, minimalist approach, assuming that infrastructure issues are rather routine and, for most part, are taken care of by external vendors and subcontractors, such as utilities, telephone companies, courier services, etc. At AAA Inc. only production equipment maintenance and operation of the IT system are performed in-house.*

**6.3.1 Buildings, workspace and associated utilities**

- 6.3.1.1 Infrastructure and facilities, such as buildings, workspaces and associated utilities, etc., are appropriate and are properly maintained to achieve conformity to product requirements.
- 6.3.1.2 Departmental managers are responsible for identifying the need and requirements for new, and/or modification or repair of existing infrastructure and facilities in their departments. Requests for changes and/or expansions of facilities are submitted to the top management for review and approval.
- 6.3.1.3 Maintenance of buildings and facilities is performed by external contractors. This includes regularly scheduled maintenance of lighting systems, air conditioning and heating systems, landscaping, and cleaning. Repairs of buildings and other such facilities are contracted as needed. Purchasing is responsible for coordinating and managing maintenance contracts.

**6.3.2 Process equipment**

- 6.3.2.1 Procurement of new, and/or modification of existing process equipment (including hardware and software) are planned in conjunction with development of manufacturing processes, as defined in this manual in ***QM 7.1 Planning of Product Realization*** and Operational Procedure ***QOP-71-01 Production Planning and Risk Management***.

**6.3.3 Supporting services**

- 6.3.3.1 Supporting services required by **<Company Name>** include transportation, communication, and IT services:
  - Transportation services are purchased from parcel delivery and courier services, and from trucking or other transportation companies or consolidators, as required. Transportation services are purchased in accordance with Operational Procedures ***QOP-74-01 Supplier Evaluation and Monitoring***, and ***QOP-74-02 Purchasing***.
  - Communication services are provided by various telephone, wireless, and internet access companies. Purchasing is responsible for administrating and coordinating these contracts.
  - IT systems are designed and implemented by external consultants, while the day-to-day operating of the systems is the responsibility of the **<Information Technology (IT) Manager>**. The **<IT Manager>** is responsible for selecting IT consultants and for administrating IT contracts.

*This clause is based on the assumption that supporting services and maintenance of facilities are mostly subcontracted, and their management is not terribly complicated or important. Most companies will not fit this minimalist assumption, and will have to further develop this section to describe their actual arrangements. For example, if you operate your own fleet of delivery vehicles you should describe in more detail how this activity is*

*managed and how is it integrated into the quality system. Even if your company generally fits this description, you should edit this section to ensure that it exactly describes how these things are actually done in your company.*

#### **6.3.4 Equipment Maintenance**

6.3.5 Key process equipment, machines, hardware, and software are regularly maintained in accordance with maintenance plans specified by equipment manufacturers or departmental managers responsible for the equipment. Requirements for the maintenance of production equipment are specified in Operational Procedure ***QOP-63-01 Equipment Maintenance***.

### **6.4 WORK ENVIRONMENT**

#### **6.4.1 Human factors**

*This section addresses general requirements for work environment as they are usually interpreted for an ISO 9001 system. In 13485 the emphasis is shifted to controlling the physical environment in production areas rather than "workplace" environment. If you don't need to comply with ISO 9001 you can delete this section.*

6.4.1.1 **<Human Resources>** and departmental managers are responsible for ensuring suitable physical, social and psychological conditions in the workplace. This is to include such aspects as temperature, lighting, and cleanliness; as well as language and interaction between employees.

6.4.1.2 **<Production>** and **<Quality>** are responsible for identifying those operations where extreme environmental conditions could impact quality performance of personnel and result in product nonconformities. Where appropriate, limits of exposure and/or mitigating measures are defined and implemented for these operations.

*These conditions may be extremely low or high temperature, excessive noise, or other such factors which, although legally acceptable, may adversely impact quality performance. Mitigating measures would be limits on the time of exposure, more frequent breaks, protective gear and equipment, automation of the process, etc. Delete this whole clause if it isn't relevant.*

6.4.1.3 Health and safety management system is independent form the quality management system. It is administrated by Human Resources and is documented in the Health and Safety (H&S) manual.

*For legal and compliance reasons, it is always a good idea to keep Health and Safety (H&S) management system separate from quality management. Although it may be tempting to combine the two systems to improve administrative efficiency, the problem is that H&S is, at least in the US, regulated by law, with potentially legal consequences. Edit this section to accurately describe how H&S is administrated in your company.*

#### **6.4.2 Work environment in production and storage areas**

*The highlighted aspects of environmental control are rephrased ISO 13485 clauses 6.4 a) through d). Delete any of the items that don't apply at all to your company. But don't go too far. Such issues as general cleanliness, clothing, and contamination control apply pretty much everywhere. Coordinate with procedure QOP-64-01.*

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6.4.2.1 Work environment is properly controlled in areas where environmental conditions could have an adverse effect on product quality. Operational Procedure QOP-64-01 Production and Work Environment defines the management system for environmental control. The following aspects are controlled:

- **Health, cleanliness and clothing of personnel:** If contact between personnel and the product or work environment could adversely affect the quality of the product, requirements for health, cleanliness and clothing of personnel are established and documented;
- **Work environment conditions:** If work environment conditions can have an adverse effect on product quality, requirements for the work environment conditions and procedures to monitor and control the environment are defined and documented. Environmental control systems are periodically inspected to verify that the system, including necessary equipment is adequate and functioning properly;  
*The last sentence is from CFR 820.70(c).*
- **Contaminated product:** If appropriate, special arrangements are established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product , the work environment or personnel.
- **Training:** Personnel who work under special environmental conditions are appropriately trained. Personnel who must work temporarily, or for any other reason enter environmentally controlled areas are also trained in appropriate procedures or are supervised by a trained person.